

FOR: CUTTER LABORATORIES
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FOR IMMEDIATE RELEASE

EMERYVILLE, CA, November 1, 1983 -- Cutter Laboratories today announced the voluntary withdrawal from the market of 16 lots of Factors VIII and IX, plasma concentrates used by hemophiliacs to promote blood coagulation and help them lead more normal and healthy lives.

The company said the product being withdrawn contained plasma from a donor in Austin, Texas, who died on October 21 of an opportunistic disease associated with Acquired Immune Deficiency Syndrome (AIDS). Each lot of the products consists of quantities averaging about 4,000 individual vials of the product and represents many thousands of separate individual plasma donations. No adverse reactions involving these lots have been reported.

"Cutter contacted the FDA immediately upon hearing of the death of the Austin man," reported Bud Modersbach, Cutter spokesman. "Although medical authorities consider the possibility of AIDS being transmitted through these products exceedingly remote, Cutter is taking the action on its own initiative as a precautionary measure."

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All of the product being withdrawn was produced at a Cutter facility in Clayton, North Carolina, which -- among other sources -- obtains plasma from the donor center in Austin where the AIDS victim had donated plasma between November, 1982 and September, 1983, prior to his hospitalization. Cutter's Berkeley, California plant does not use plasma from the Austin Center, Modersbach emphasized.

Modersbach said that plasma donors at all plasma centers are given physical examinations, with special emphasis on identifying AIDS symptoms -- including fever, enlargement of lymph glands and sudden, unexplained weight loss. Donors are also required to certify that they are not members of the high-risk groups for AIDS, which includes homosexuals and intravenous drug users.

"Records at the Austin plasma center show that the individual had no symptoms of AIDS, and he did not identify himself as a member of a high-risk group," Modersbach said. "After admission to the hospital, he was diagnosed through a lung biopsy as suffering from Pneumocystis Carinii Pneumonia, a disease common in AIDS patients."

The firm has determined that adequate supplies of the products will be available after the withdrawal. Cutter expects to have a heat-treated product available in the near future. This method is believed to further minimize the possibility of transmission through the products.

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Modersbach said night letters have been sent to all hospitals and other customers who received product that contained plasma donated by the individual, both in the United States and abroad. Copies of these letters were also sent to all hemophilia treatment centers. He identified the lot numbers as follows, emphasizing that these are the only products and lots involved:

Konyne^R Factor IX Complex (Human)

<u>Lot</u>	<u>Product Code</u>
NC 9117	620-20

Koate^R Antihemophilic Factor (Human)

<u>Lot</u>	<u>Product Code</u>
NC 8458	650-30
NC 8460	650-30
NC 8461	650-30
NC 8462	650-70
*NC 8465	650-72
*NC 8466	650-71
NC 8470	650-30
	650-77
NC 8474	650-30
NC 8475	650-20
	650-20S
	650-76
NC 8476	650-20
NC 8477	650-50
NC 8479	650-30Z
NC 8480	650-30Z
	650-77
NC 8489	650-30Z
NC 8493	650-20Z

*Exported

A toll-free line will be set up to receive questions regarding lot numbers and product return: 800-227-1762 (outside California); 800-227-3219 (in California).